

EXHIBIT A

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Clerk of Court
Superior Court of CA,
County of Santa Clara
22CV393988
Reviewed By: M. Dominguez

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SUPERIOR COURT FOR THE STATE OF CALIFORNIA
COUNTY OF SANTA CLARA
UNLIMITED CIVIL

LAN FENG, an individual,

Plaintiff,

vs.

ASC THERAPEUTICS, INC., a Delaware
corporation, and DOES 1-50, inclusive,

Defendants.

Case No.: 22CV393988

COMPLAINT FOR:

**(1) WRONGFUL TERMINATION IN
VIOLATION OF PUBLIC POLICY**

**(2) RETALIATION IN VIOLATION OF
LABOR CODE § 1102.5**

**(3) VIOLATION OF 31 U.S.C. § 3730
(FEDERAL FALSE CLAIMS ACT
RETALIATION)**

DEMAND FOR JURY TRIAL

Plaintiff LAN FENG, demanding trial by jury of all issues joined herein, alleges as follows:

INTRODUCTION

1. In November 2020, Plaintiff Lan Feng (“Feng” or “Plaintiff”) was hired by ASC Therapeutics, Inc. (collectively with Doe Defendants as “Defendants”) to serve as their VP of Quality. Defendants produce and develop products used in gene and cell therapy, so safety is of paramount importance.

1 defendants is legally responsible for the occurrences herein alleged and that Plaintiff's losses
2 and damages are the result of their wrongful conduct.

3 9. Plaintiff is informed and believes and thereon alleges that at all relevant times
4 herein, all Defendants and Does 1-50 were the agents, joint employers, alter egos, and/or joint
5 ventures of, or working in concert with the other Defendants, and were acting within the course
6 and scope of such agency, employment, joint venture and/or concerted activity. To the extent
7 that said conduct and/or omissions were perpetrated by Defendants and their agents,
8 Defendants confirmed and ratified said conduct and/or omissions.

9 **JURISDICTION AND VENUE**

10 10. The monetary value of Plaintiff's claims exceeds \$25,000.

11 11. The amount in controversy herein is within the jurisdiction of this Court.

12 12. Defendant ASC Therapeutics, Inc. is a Delaware corporation authorized to do
13 and doing business within the state of California. Its California headquarters are located at 521
14 Cottonwood Drive, Suite 111, Milpitas, CA 95035, County of Santa Clara.

15 13. Plaintiff alleges on information and belief that Does 1-50 were and are
16 California corporations or other business entities or individuals authorized to do and who did
17 business in the County of Santa Clara.

18 14. The acts, omissions, damages, and injuries that form the basis of this lawsuit
19 were sustained in the County of Santa Clara.

20 **FACTUAL ALLEGATIONS**

21 15. Defendant ASC Therapeutics, Inc. ("ASC") is a biopharmaceutical company
22 specializing in development of products for use in gene therapy and cell therapy. It has two
23 products in clinical stage – ASC618 and ASC930.

24 16. On October 23, 2020, ASC Therapeutics, Inc. offered Feng the position of VP
25 of Quality. Feng's first day of work was November 16, 2020.

26 17. As Head of Quality, one of Feng's primary responsibilities was to ensure that
27 the internal and external activities of the company and its employees were in compliance with
28 all relevant CFR (Code of Federal Regulations) and FDA regulations, including GMP (Good

1 Manufacturing Practice) Regulations. She was further responsible for creating, reviewing, and
2 approving the company's internal SOPs (Standard Operating Procedures) related to such
3 compliance, overseeing the GMP activities, and reviewing the internal and external documents
4 and records to ensure compliance and data integrity.

5 18. Soon after she started working, Feng observed that Lijing Li ("Li"), the Director
6 of CMC (Chemistry, Manufacturing, and Control), lacked the proper personnel qualifications
7 as required by the FDA's GMP for Finished Pharmaceuticals. Specifically, amongst other
8 issues, Li was in violation of 21 CFR 211.25(b). This subsection stipulates that people
9 involved in product manufacturing and processing should possess adequate, sufficient, and
10 relevant education, training, and experiences, including familiarity with GMP regulations and
11 quality.

12 19. Li's lack of competence was demonstrated on multiple occasions. For example,
13 she failed to provide critical records, including documents of the products' information, to
14 Feng, ASC's Quality Head. This constituted another CFR violation; 21 CFR 211.192 requires
15 all drug production and control records to be reviewed for compliance and approved by the QA
16 unit. Furthermore, Li unilaterally made changes to specifications and processes without
17 consulting Feng/QA, and without their approval, in clear violation of CFR stipulations and the
18 company's own internal procedures. For pharmaceutical drugs intended for use in humans, any
19 and all changes in the manufacturing processes and quality specifications must be made
20 pursuant to applicable laws and regulations, including the GMP. For example, 21 CFR
21 211.100 explicitly states that any changes to product production or process control procedures
22 must be reviewed and approved by an independent QA unit.

23 20. Feng began confronting Li about the aforementioned and other non-compliance
24 issues in December 2020. Li's general response was that she made all executive decisions by
25 herself before Feng joined the company, and that QA was only slowing down the company's
26 projects.

27 21. On December 11, 2020, Feng had a conversation with Ruhong Jiang, President
28 and CEO of ASC Therapeutics. In it, she voiced her concern about various non-compliance

1 issues related to Li (not sharing required data records or GMP manufacturing activities with
2 QA, keeping QA out of the loop on critical decisions, not exhibiting proper understanding of
3 relevant external and internal regulations, etc.). Feng expressed similar concerns in further
4 conversations with Mr. Jiang on December 15 and December 27. In yet another conversation
5 on January 12, 2021, Mr. Jiang acknowledged that Li did not share information with other
6 people, including with her own consultant.

7 22. On February 3, 2021, in a phone conversation with Mr. Jiang, Feng reported
8 another GMP violation by Li. Namely, that the latter changed a specification without QA's
9 approval.

10 23. On February 5, 2021, Feng found out that one of ASC's vendors for the tissue
11 cell sources for ASC930, was not qualified per ASC's internal procedures and per 21 CFR
12 1271. The FDA enforces Good Tissue Practices (GTP) through the latter. The vendor did not
13 provide a donor eligibility statement in a timely manner, and thus did not meet the relevant 21
14 CFR 1271 requirements. Additional vendor activities went against the GTP provisions as well.

15 24. On February 8, 2021, during a senior leadership team (SLT) meeting, Feng
16 raised her serious concerns about the vendor's lack of qualifications, the donor eligibility issues
17 that violated 21 CFR 127, and other related issues. But she was ignored.

18 25. Around March 2021, Feng had a meeting with Mr. Jiang. During the meeting,
19 Mr. Jiang acknowledged that he had recently learned of Li's limited experience with GMP and
20 the compliance issues in general.

21 26. On March 7, 2021, Feng confronted Li in a phone conversation regarding the
22 noncompliance issues by another vendor, Vigene. Li responded by saying "I am reporting to
23 CEO, not you," and hung up the phone. Feng emailed Mr. Jiang, again complaining of Li's
24 non-compliance with GMP regulations.

25 27. On March 8, 2021, Feng had a one-on-one meeting with Mr. Jiang. She
26 emphasized the need for QA to be able to make independent decisions, especially in light of
27 Li's non-compliance with regulations and internal/external SOPs. Mr. Jiang did not offer a
28 solution to the issues raised.

1 28. On April 6, 2021, Feng reported another GMP violation via email to Mr. Jiang.
2 She expressed concerns that the violations were willful and not simply due to lack of
3 knowledge. Mr. Jiang emailed Li that same day, asking her to “work closely with the quality
4 head.” However, Li continued to commit violations and disregard Feng’s role and duties.
5 Feng continued to relay her concerns to the company and continued to be ignored.

6 29. In fact, despite the numerous warnings Feng provided about Li’s obvious and
7 repeated breaches of regulations and external/internal procedures, Li was promoted to a Senior
8 Director position on August 1, 2021. Based on this development and other feedback that Feng
9 had received, she realized that the company and its CEO favored project expediency and future
10 profits prospects over compliance and, ultimately, over patients’ safety. This was further
11 corroborated by the facts discussed below.

12 30. During the period between January and May 2021, two separate contamination
13 events occurred that affected ASC618. Li was unable to handle those issues and refused to
14 take responsibility as a project lead. On May 7, 2021, Feng presented the ASC618 and
15 ASC930 production lots’ status from an QA point of view in an SLT meeting, emphasizing the
16 need for coordination with Contract Manufacturing Organizations (CMOs) on clinical trial
17 materials production matters. ASC set up a Task Force Team which, among other things, had
18 to educate Li on her duties and responsibilities during a May 17, 2021 meeting.

19 31. In a clear violation of federal regulations, ASC, through its SLT, chose not to
20 report the contamination incidents to the FDA. Specifically, ASC misled the FDA in its IND
21 (Investigational New Drug) application by not updating/reporting the contamination issues in
22 its clinical materials. This decision was made despite the fact that ASC was aware of a CMO
23 conclusion that the same bacteria contaminated two separate GMP batches as identified in the
24 plasmid materials. By doing so, it violated the provisions of CPG (Compliance Policy Guide)
25 Sec. 120.100, as this conduct constituted an “untrue statement of material facts” as defined by
26 the related FDA’s AIP (Application Integrity Policy).

27 32. On July 5, 2021, the FDA, oblivious to the blatant violations present in the IND
28 application, authorized ASC to use ASC618 for first-in-human clinical testing. In hearing that

1 news, Mr. Jiang said in an SLT meeting that the value of the company could increase tenfold
2 should it obtain the first-in-human data.

3 33. On or around July 17, 2021, ASC also applied for and was granted a Drug
4 Manufacturing License (License Number: 113832) by the State of California Department of
5 Public Health Food and Drug Branch. On information and belief, this license was obtained by
6 ASC's failure to report its contamination incidents, as well as their failure to disclose their
7 noncompliance with regulations such as California Health and Safety Code §§ 111630, 111635,
8 and 111640. These regulations are meant to ensure the accuracy of licensing application and
9 permit inspections of drug-manufacturing facilities.

10 34. Following the February 2021 SLT meeting, up until her termination, Feng
11 insisted on reviewing the raw data related to the company's IND application for ASC618. This
12 fell firmly within the scope of her duties. She was once again ignored by SLT, when she
13 expressed her concerns about moving forward despite known contamination.

14 35. On August 5, 2021, Feng emailed Mr. Jiang regarding yet another instance of
15 Li's non-compliance. Li kicked Feng out of an email group in which Feng's role obligated her
16 to be included. Li denied this act, despite the evidence to the contrary.

17 36. On August 6, 2021, during a SLT meeting (with Mr. Jiang and Li present), Feng
18 again raised her non-compliance concerns. The implications were of great import: based on the
19 gravity of the non-compliance issues, ASC618 would likely be rejected for use in human trials,
20 despite the recent FDA approval. Li responded this was the first time she heard there were
21 non-compliance issues, a statement which was misleading at best. Mr. Jiang suggested that
22 they work together to resolve the issues. Later that day, in response to Li's email from the prior
23 day, he also suggested "a face-to-face meeting with [Li] to train her on GMP compliance
24 relevant issues."

25 37. On August 8, 2021, Feng called Mr. Jiang to inquire whether he had been
26 conveying her concerns to Li. While Mr. Jiang stated that he had, Feng was doubtful about the
27 veracity of his assurances.

1 38. On August 9, 2021, Feng emailed Mr. Jiang, SLT members, and Nan Sheng in
2 HR about Li's unilateral decision to invite external Contract Manufacturing Organizations to
3 discuss compliance issues following the August 6th SLT meeting, as the compliance issues that
4 needed addressing were internal (i.e., Li's).

5 39. Later that day, Feng sent an email to HR (Nan Sheng) complaining of
6 "workplace coercion and harassment." In this email, she noted Li's bullying and lies related to
7 her compliance breaches.

8 40. On August 12, 2021, Nan Sheng told Feng, in person, that she should not have
9 sent an email to SLT, and Mr. Jiang was not happy about it.

10 41. On August 16, 2021, Feng was placed on PIP (Performance Improvement
11 Program) for "inappropriately sen[ding] email to leadership group." She complained to Mr.
12 Jiang about the PIP that same day. While Li was put on PIP as well, this was likely done with
13 the intent of masking the major, unresolved compliance issues behind a contrived pretextual
14 conflict between two employees – Feng and Li.

15 42. The following day, ASC's Chief Medical Officer (who performs some HR
16 functions as well), emailed Feng and Li stating the PIP was on hold. Feng then sent an email to
17 both the Chief Medical Officer and HR, stating: "...I have tried to communicate my concerns
18 in many ways (Lijing, Ruhong, [...], Nan, and others) over several months, and the company
19 failed to stop Lijing's rude behavior and noncompliance activities... all GMP related SOPs are
20 enforceable by gov. agency. It is appropriate to let the senior leader team be aware of the
21 critical concerns, my constructive messages [would] only make the company better in the long
22 term."

23 43. On August 20, 2021, an external investigator hired by ASC, interviewed Feng
24 regarding her complaints. Feng provided her with examples of non-compliance, lack of proper
25 competence, and hostile working environment at the company.

26 44. On September 2, 2021, Ms. Sheng emailed Feng to suggest they should review
27 the investigator's report at the office at 11:00 a.m. the following day. On September 3, 2021,
28 Feng met with HR and ASC's Chief Medical Officer. They told her she must accept PIP, or

1 she would be terminated. Feng refused to accept PIP and was thus terminated, effective the
 2 same day. Ms. Sheng was the author of the termination letter, which did not cite to any
 3 specific reasons for the firing.

4 **FIRST CAUSE OF ACTION**

5 **WRONGFUL TERMINATION IN VIOLATION OF PUBLIC POLICY**

6 **(Against all corporate Defendants)**

7 45. Plaintiff repeats and re-alleges the allegations contained in the preceding
 8 paragraphs, inclusive, and incorporates the same by reference as though fully set forth herein.

9 46. Plaintiff is informed and believes, and based thereon alleges, that her
 10 termination was brought about by the wrongful conduct of Defendants. Such conduct was in
 11 violation of the public policy of the State of California as set forth in Labor Code sections
 12 1102.5 and Government Code section 12650 *et seq.*, including Government Code section
 13 12653.

14 47. As alleged above, ASC terminated Plaintiff's employment, depriving her of its
 15 attendant benefits and compensation, immediately in the wake of and because of her
 16 complaints about dangerous/defective products that the company was releasing into the
 17 commerce stream for human clinical trials. Plaintiff, in no uncertain words, complained to the
 18 company about flaws in its manufacturing process that created a substantial risk to public
 19 health and safety, including the threat of infection and even death of patients.

20 48. The effect of the above-described termination by the company has been to
 21 deprive Plaintiff of employment opportunities and to otherwise adversely affect her status as an
 22 employee because of her opposition, refusal to engage in and resistance to unlawful conduct.

23 49. As a proximate result of Plaintiff's termination by Defendants, Plaintiff has
 24 suffered and continues to suffer harm, including but not limited to, lost earnings and other
 25 employment benefits, loss of future employment benefits, humiliation, emotional distress, and
 26 mental pain and anguish, all to her damage in an amount to be proven at trial but exceeding the
 27 minimum jurisdictional limits of this Court.

1 mental pain and anguish, all to her damage in an amount to be proven at trial but exceeding the
2 minimum jurisdictional limits of this Court.

3 59. In doing the acts herein alleged, Defendants acted with oppression, fraud, malice
4 and in conscious disregard of Plaintiff's rights. Plaintiff is therefore entitled to punitive
5 damages in an amount according to proof at trial.

6 60. Plaintiff has also incurred and continues to incur attorneys' fees and legal
7 expenses in an amount according to proof at trial.

8 61. Plaintiff requests relief as described below.

THIRD CAUSE OF ACTION

VIOLATION OF 31 U.S.C. § 3730

FEDERAL FALSE CLAIMS ACT RETALIATION

11 62. Plaintiff repeats and re-alleges the allegations contained in the preceding
12 paragraphs, inclusive, and incorporates the same by reference as though fully set forth herein.

13 63. By virtue of their work, Defendants receive millions of dollars in government
14 funding. Though not all of this is granted to ASC directly, it can be traced to individuals and
15 entities that receive funds to be spent or used on the Government's behalf or to advance a
16 Government program or interest. On information and belief, funds that have been granted to
17 ASC include: at least \$3.8 million paid by the National Institutes of Health (NIH) to ASC's
18 parent company, Applied Stemcell, Inc., since 2014, which was at least in part used for funding
19 gene editing technology related to ASC618; \$1,525,431 from NIH to H. Trent Spencer, Ph.D.
20 and Christopher Doering, whose work on gene therapy for hemophilia using those funds forms
21 the basis of ASC618; and at least \$4,072,684 to Spencer and Doering's company Expression
22 Therapeutics, which was used to produce work to which ASC acquired the rights and utilized
23 in developing its projects.

24 64. As part of certifications that Defendants made and, on information and belief,
25 continue to make, in order to obtain such funding, Defendants represent that their
26 manufacturing processes create drugs that are safely derived from cells, and which can be used
27 to treat intractable diseases and conduct gene/cell therapy in humans. Additionally, on
28

1 information and belief, Defendants represented and represent that the company follows current
 2 Good Manufacturing Practices (GMPs) and Good Tissue Practices (GTPs) promulgated by the
 3 U.S. Food and Drug Administration (FDA), the Compliance Policy Guide, the FDA's
 4 Application Integrity Policy, relevant Code of Federal Regulations, and their own internal
 5 quality control and safety precautions. These are all standards designed to protect the public
 6 from dangers to consumer/patient health and safety, and consequently are material information.

7 65. Defendants made these representations despite knowing of the falsity of the
 8 statements.

9 66. Plaintiff's protected activity, as described above, included efforts to stop,
 10 complaints about, and refusal to engage in or cover up violations of these standards, and by
 11 extension, the false statements submitted to the companies and individuals providing ASC with
 12 funding from the government. These statements are those that ASC used and uses in order to
 13 secure substantial funding.

14 67. Immediately following and in retaliation for her protected activity and efforts to
 15 stop what amounts to violations of the Federal False Claims Act, the company terminated
 16 Plaintiff's employment.

17 68. Plaintiff's protected activity was a substantial motivating factor for the
 18 company's termination of her employment and thus constituted unlawful retaliation in violation
 19 of 31 U.S.C. § 3730.

20 69. The effect of the above actions and omissions by Defendants has been to
 21 deprive Plaintiff of employment opportunities and to otherwise adversely affect her status as an
 22 employee because of her opposition and/or resistance to unlawful conduct.

23 70. As a proximate result of Plaintiff's termination by Defendants, Plaintiff has
 24 suffered and continues to suffer harm, including but not limited to, lost earnings and other
 25 employment benefits, loss of future employment benefits, humiliation, emotional distress, and
 26 mental pain and anguish, all to her damage in an amount to be proven at trial but exceeding the
 27 minimum jurisdictional limits of this Court.

72. Plaintiff requests relief as described below.

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PRAYER FOR RELIEF

WHEREFORE, Plaintiff seeks relief from this Court in the following respects:

1. For special and general damages according to proof;
2. For double damages pursuant to California Government Code section 12653 and 31 U.S.C. § 3730(h);
3. For punitive damages;
4. For a permanent injunction prohibiting Defendants from engaging in violation of relevant provisions of the California Labor Code;
5. For costs of suit incurred herein;
6. For attorneys' fees on causes of action where fees are available by law, including those recoverable pursuant to California Labor Code 1102.5 and 31 U.S.C. § 3730(h);
7. For prejudgment and post-judgment interest as available by law; and
8. For such other and further relief as this Court may deem just and proper.

2. For double damages pursuant to California Government Code section 12653 and 31 U.S.C. § 3730(h);

3. For punitive damages;

4. For a permanent injunction prohibiting Defendants from engaging in violation of relevant provisions of the California Labor Code;

5. For costs of suit incurred herein;

6. For attorneys' fees on causes of action where fees are available by law, including those recoverable pursuant to California Labor Code 1102.5 and 31 U.S.C. § 3730(h);

7. For prejudgment and post-judgment interest as available by law; and

8. For such other and further relief as this Court may deem just and proper.

Dated: January 31, 2022

Respectfully submitted,

By: s/ David Markevitch

David Markevitch
Affeld Grivakes LLP
Attorney for Plaintiff

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a jury trial for each cause of action on which she is entitled to a jury trial.

Dated: January 31, 2022

Respectfully submitted,

By: s/ David Markevitch

David Markevitch
Affeld Grivakes LLP
Attorney for Plaintiff